Assessment of three-dimensional stent-graft dynamics by using fluoroscopic roentgenographic stereophotogrammetric analysis

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Objective: **To validate the use of fluoroscopic roentgenographic stereophotogrammetric analysis (FRSA) for its feasibility and accuracy for measuring the three-dimensional dynamic motion of stent grafts.**

Methods: **A digital biplane fluoroscopy setup was calibrated (Siemens Axiom Artis dBc). Stereo images were acquired of a static aortic model with a stent graft in different axial positions, imposed by a micromanipulator. The three-dimensional measurement error of FRSA was determined by comparing FRSA measurements with the micromanipulator. An aortic model with a stent graft was constructed and connected to an artificial circulation with a physiological flow and pressure profile. Markers were added to the spine (tantalum spherical markers; diameter 1 mm) and stent (welding tin; diameter 1 mm). The three-dimensional measurement precision was determined by measuring the position of a single (stable) spine marker during two pulsatile cycles. Finally, three-dimensional stent marker motion was analyzed with a frame rate of 30 images per second, including three-dimensional marker position (change), diameter change, and center of circle position change.**

Results: **The mean error of FRSA measurement of displacement was 0.003 mm (SD, 0.019 mm; maximum error, 0.058 mm). A very high precision of position measurement was found (SD, 0.009-0.015 mm). During pulsatile motion, the position (changes) of the markers could be assessed in the x, y, and z directions, as well as the stent diameter change and center of circle position change.**

Conclusions: **FRSA has proven to be a method with very high accuracy and temporal resolution to measure three-dimensional stent-graft motion in a pulsatile environment. This technique has the potential to contribute significantly to the knowledge of stent-graft behavior after endovascular aneurysm repair and improvements in stent-graft design. The technique is ready for clinical testing. (J Vasc Surg 2007;46:773-9.)**

Clinical Relevance: **Until now, three-dimensional stent-graft motion due to the cardiac cycle could not be quantified in vivo. Fluoroscopic roentgenographic stereophotogrammetric analysis (FRSA) uses a new combination of two techniques: digital biplane fluoroscopy and roentgenographic stereo photogrammetric analysis. This in vitro study describes the validation and feasibility of FRSA. With FRSA it becomes possible to measure three-dimensional motion of stent-graft markers with a very high accuracy and precision. Using this technique, clinical studies can be performed to better understand stent-graft motion and the repetitive forces acting on the graft. Knowledge of three-dimensional motion can have a significant effect on stent-graft design and outcome.**

Endovascular repair (EVAR) of an abdominal aortic aneurysm is a widely used therapeutic alternative to open repair. A known problem with this technique is that the stent graft can fail as a result of device defects caused by the continuous and significant forces of pulsatile blood flow. These failures have potential detrimental effects on patient health and safety.[1,2] An important problem of understanding failures is that it is difficult to study and measure aorta and stent graft dynamics after EVAR, and clinical data are therefore limited. For the development, improvement, and evaluation of new and current stent grafts, it is of significant interest to understand aorta and stent-graft dynamics in vivo. Modeling of these blood flow–related dynamics is very difficult. Subsequently, bench-testing of repetitive motion of stent grafts is often inadequate and can lead to faulty stent graft design.

Currently, cinegraphic computed tomography (CT) and magnetic resonance imaging (MRI) can be used to measure aorta and stent graft motion during the cardiac cycle.[3-5] An important limitation of these imaging modalities is that motion can be measured only in one plane. Three-dimensional motion of specific points of a stent graft cannot be quantified. Furthermore, the spatial resolution of these techniques is limited.[5]

Roentgenographic stereophotogrammetric analysis (RSA) is a tool to assess marker positions by using stereo roentgenographic images.[6,7] This technique has proven to

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Competition of interest: none.

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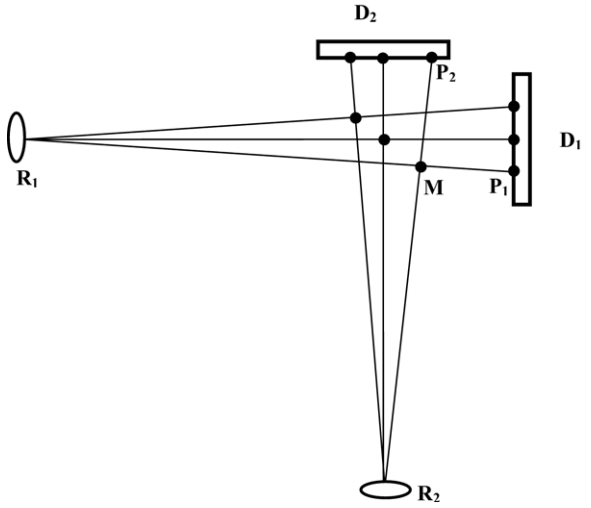

Fig 1. Schematic drawing of the fluoroscopic roentgenographic stereophotogrammetric analysis technique. The positions of the roentgen foci (R_1 and R_2), the detectors (D_1 and D_2), and their relative positions are known by calibration of the setup. Graft markers give projections P^1 and P^2 on the detectors. With a calibrated setup, projection lines can be reconstructed. Calculation of intersections M of these projection lines in space gives the positions of the markers.

be highly accurate and is used to measure prosthesis migration in the relatively static environment of follow-up after joint replacement surgery.[8-11] Recently, RSA was introduced as an accurate tool to measure stent graft migration during post-EVAR surveillance.[12,13] RSA cannot be used to measure stent graft motion during the cardiac cycle, because it uses one single stereo image acquired with two regular single-shot x-ray machines. It is therefore impossible to acquire a rapid sequence of calibrated images.

With the development of digital biplane fluoroscopic imaging systems, accurate measurement of three-dimensional stent-graft motion during the cardiac cycle can become possible by combining stereo fluoroscopy with the RSA technique. This could enable in vivo motion analysis of stent grafts during the cardiac cycle. We validated the use of this combination of techniques—fluoroscopic RSA, or FRSA—for its feasibility and accuracy for measuring the three-dimensional dynamic motion of stent grafts.

METHODS

The concept of FRSA

RSA is performed by calculating the point of intersection of two projection lines of a marker in space by using calibrated stereo roentgenographic imaging (Fig 1).[6-13] FRSA uses high-resolution digital stereo fluoroscopic images that are calibrated according to the same principles as RSA to calculate marker positions. Fast image acquisition and high frame rate theoretically enable accurate measurement of stent-graft motion in high spatial and temporal resolution.

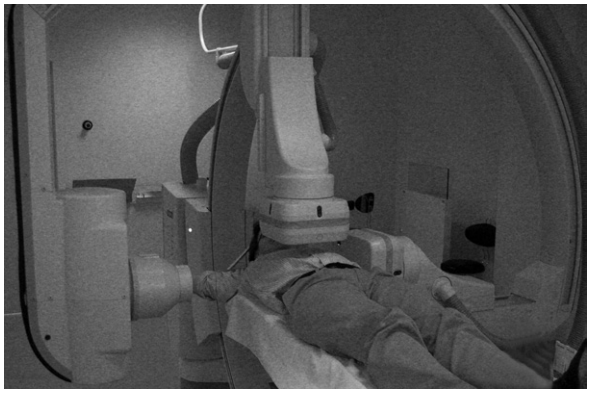

Fig 2. Clinical setup of the biplane fluoroscope.

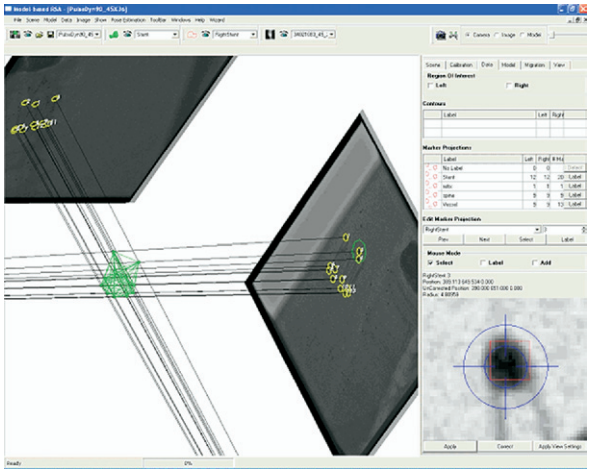

Fig 3. Image of the software with reconstruction of the stent graft in space. The two images of a stereo image pair, a lateral and a posteroanterior image, are visible. The calculated projection lines and their points of intersection depicting marker positions are also shown. The right lower corner shows a detected stent marker.

FRSA setup

We used a Siemens Axiom Artis dBc imaging system (Siemens Nederland NV Medical Solutions, The Hague, The Netherlands) (Fig 2), which consists of two C-arms with digital flat-panel roentgenographic detectors. The focus-to-detector distance was set at 95 cm. The two C-arms were positioned at a 90° angle to produce a posterior-anterior image and a lateral image. The images were acquired and stored in 1024 × 1024 pixel, 14-bit grayscale resolution (Fig 3). The frame rate was 30 bidirectional images per second. Each stereo image is acquired as 2 separate alternating images, resulting in 60 alternating images per second. The exposure time of each image was 4 milliseconds. The time between the posterior-anterior image and lateral image was 12.7 milliseconds. For each analysis reported in this study, a 1.5-second run (45 stereo images) was acquired.

The image pairs were analyzed by using model-based RSA software (MB-RSA; MEDIS Specials, Leiden, The

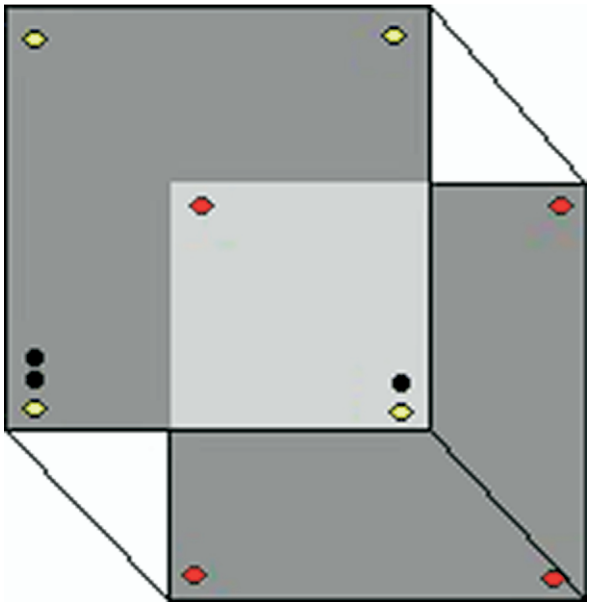

Fig 4. Calibration object. Plexiglas block (dimensions, w × d × h: 8 × 8 × 5 cm). In every corner is one tantalum marker (diameter, 1 mm; *red* and *yellow*). In the top layer are three extra markers (diameter, 2 mm; *black*) for ease of identification of the different markers.

Netherlands) to calculate the relative three-dimensional marker positions.[8-11] No image reconstruction is required before analysis of the image pairs.

FRSA setup calibration. To calibrate the setup, a single focus run of a specially designed acrylic (PMMA, Vink Kunststoffen, Didam, The Netherlands) calibration box was acquired with each of the two C-arms.[14] From each run, a randomly chosen image was analyzed by using the calibration algorithm as published previously.[14] This algorithm provides the calibration parameters to correct for image scale and geometric distortion, as well as the position of the roentgenographic focus relative to the image for each C-arm. The relative position and orientation between the two C-arm images is necessary to calculate the three-dimensional marker positions by using RSA analysis. This was achieved by using a calibration object with 11 markers in known positions (Fig 4). The two images of the object were aligned to reconstruct the marker positions in space, and the calculation used to reconstruct an RSA image was reversed (Fig 1). This gave the position and orientation between the C-arms. Further analysis of the experimental images, as described below, could now be performed within this calibrated setup.

Static model experiments. A static model of an aorta with a stent graft, with markers in known positions, was placed in the setup (Fig 5). The same model was used as described previously.[12] The stent graft could be translated accurately in the aortic lumen with a micromanipulator. The stent graft was moved in the axial direction inside the aorta over 1, 1.5, and 3 mm by using the micromanipulator. The increments of the micromanipulator were accurate up to 0.01 mm according to the manufacturer, and this was confirmed by laboratory testing at our institution. The translation of the stent resulted in a three-dimensional displacement of the markers. Three random stereo images were taken from an acquisition run of each position. Five marker positions were determined by using FRSA. This was done to test for the accuracy of measurement of the relative change in position of the markers by comparing the change in x, y, and z coordinates and calculating the length of the resulting vector of displacement. Mean, standard deviation, and the minimum and maximum of the translations of the markers were measured, and the results were compared with the micromanipulator settings, used as the standard of reference. This way, the measurement error of FRSA was determined for all measurements (n = 45). These data were pooled to describe the mean error, standard deviation, and maximum measurement error of marker position change as measured by FRSA.

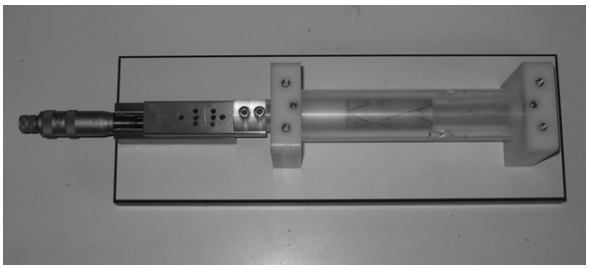

Fig 5. Static model of an aorta *(tube)* with stent graft (visible inside tube). The micromanipulator is on the left side.

Pulsatile model experiments. For measurements under flow conditions, we developed a model to simulate a pulsating aorta with a stent graft. To resemble human aorta characteristics, a fresh specimen of a porcine thoracic aorta was used, as published previously.[13] The porcine aorta was fixed to a human cadaver spine, replacing the cadaver aorta. The spine was complete with soft tissue (Fig 6). As an internal control for the experiments, the spine was marked with nine tantalum markers.

The aorta was filled with a starch solution with the same viscosity as blood. Inside the aorta, a Gianturco stent (Cook, Bjaeverskov, Denmark) was placed. The stent was marked with small drops of welding tin with a diameter of 1 mm; the stent graft markers included nine at the cranial side and three at the caudal side. We used a stent rather than a stent graft to study marker motion because FRSA uses the stents of the stent graft for analysis, identical to other radiologic imaging techniques. The model was placed in an acrylic box topped off with water to simulate soft tissue.

To test the feasibility of measuring marker motion in a clinical situation, a study of a pulsating aorta was performed. The porcine human-aorta model was connected to an artificial circulation with a physiologic flow and pressure profile, as published previously.[13,15] This induced pulsatile marker motion of the aorta and stent graft markers in the x,

Fig 6. Pulsatile flow model. A fresh specimen of a porcine aorta was positioned ventral to a preserved human spine, complete with soft tissue. The porcine aorta replaced the human aorta. The aorta is connected to a pulsatile flow generator with physiologic flow and pressure profiles.

y, and z directions. With a pulse rate set at 80 per minute, a biplane fluoroscopy run of 1.5 seconds resulted in imaging 2 pulsatile cycles. Three-dimensional marker positions of the stent markers and the control markers in the spine were determined in every stereo image.

The tantalum spine markers were used to determine measurement precision. For each stereo image, the coordinates of a randomly chosen spine marker were determined (n = 45). The x, y, and z coordinates of the markers were compared with the average of the 45 measured positions, and the standard deviation, minimum, and maximum deviation were determined. This is a measure for the precision of the position estimation of a marker in consecutive stereo images by using FRSA.

Finally, three-dimensional stent-marker motion was analyzed. The marker positions were determined for each sequential frame. The resulting series of marker positions was analyzed for marker motion. Furthermore, a circle was estimated through the nine cranial markers in every stereo image. The resulting series of circles were analyzed for change of diameter (ie, the stent graft and inner vessel diameter) and motion of the circle center, as a measure for the three-dimensional motion of the aorta–stent-graft complex. Analysis was performed with Matlab r2006B (The MathWorks, Natick, Mass).

RESULTS

By using the calibration box, the setup was tested for image distortion. No image distortion was found.

Validation studies. The mean, standard deviation, and minimum and maximum of the relative changes in position of the markers in the static stent-graft model are presented in Table I. After the measurement errors of FRSA were pooled, as compared with the micromanipulator, the mean error of three-dimensional marker motion measurement by FRSA was 0.003 mm (SD, 0.019 mm; maximum error, 0.058 mm; n = 45).

Table I. Three-dimensional changes in position of 5 markers measured by fluoroscopic roentgenographic stereophotogrammetric analysis in 3 image frames (n=15 per displacement) compared with actual displacements as imposed by the micromanipulator applied as the gold standard

	Imposed translation		
Measurements	*1 mm*	*1.5 mm*	*3 mm*
Mean	1.007	1.497	3.004
SD	0.015	0.022	0.023
Minimum	0.979	1.442	2.967
Maximum	1.025	1.513	3.030

Table II. Precision of position measurement of 1 spine marker in the 45 image frames (n = 45)

Measurement	*x (mm)*	*y (mm)*	*z (mm)*
SD	0.015	0.009	0.012
Minimum deviation	−0.032	−0.020	−0.023
Maximum deviation	0.027	0.017	0.027

The precision of three-dimensional marker position measurement by FRSA was determined by analysis of the position of one of the spine markers in 45 consecutive frames. The results are presented in Table II. The precision is expressed by the standard deviation of the measured laboratory coordinates (0.009-0.015 mm).

Measurement of stent-graft dynamics. Finally, the pulsatile dynamics of the stent graft were analyzed by using the calibrated and validated setup. There seemed to be a cyclic motion of the stent graft. This motion occurred in all directions. Fig 7, *a*, shows a schematic drawing of the stent configuration. Figure 7, *b*, shows the position (changes) of the stent graft markers during the 2 pulsatile cycles (1.5-second acquisition run; 45 images). Figure 7, *c*, shows the position (changes) of a single marker during the same period. Figure 7, *d*, shows a breakdown of this marker motion in the x, y, and z directions.

Figure 8 shows the circle that was estimated through the cranial markers of the stent graft. The cyclic diameter change of the circle is shown in Fig 9. The circle center motion is displayed in Fig 10 and shows cyclic motion of the stent in all directions.

DISCUSSION

FRSA enables highly accurate measurement of three-dimensional motion of markers on a stent graft in a pulsatile in vitro model. Axial, lateral, and rotational motion can be measured with a mean error of less than 0.01 millimeters in every direction (error, 0.003 mm; SD, 0.019 mm). The precision of three-dimensional marker position measurement by FRSA is very high, as expressed by the small standard deviation of the measurement of the x, y, and z coordinates of the markers (0.009-0.015 mm). This non-

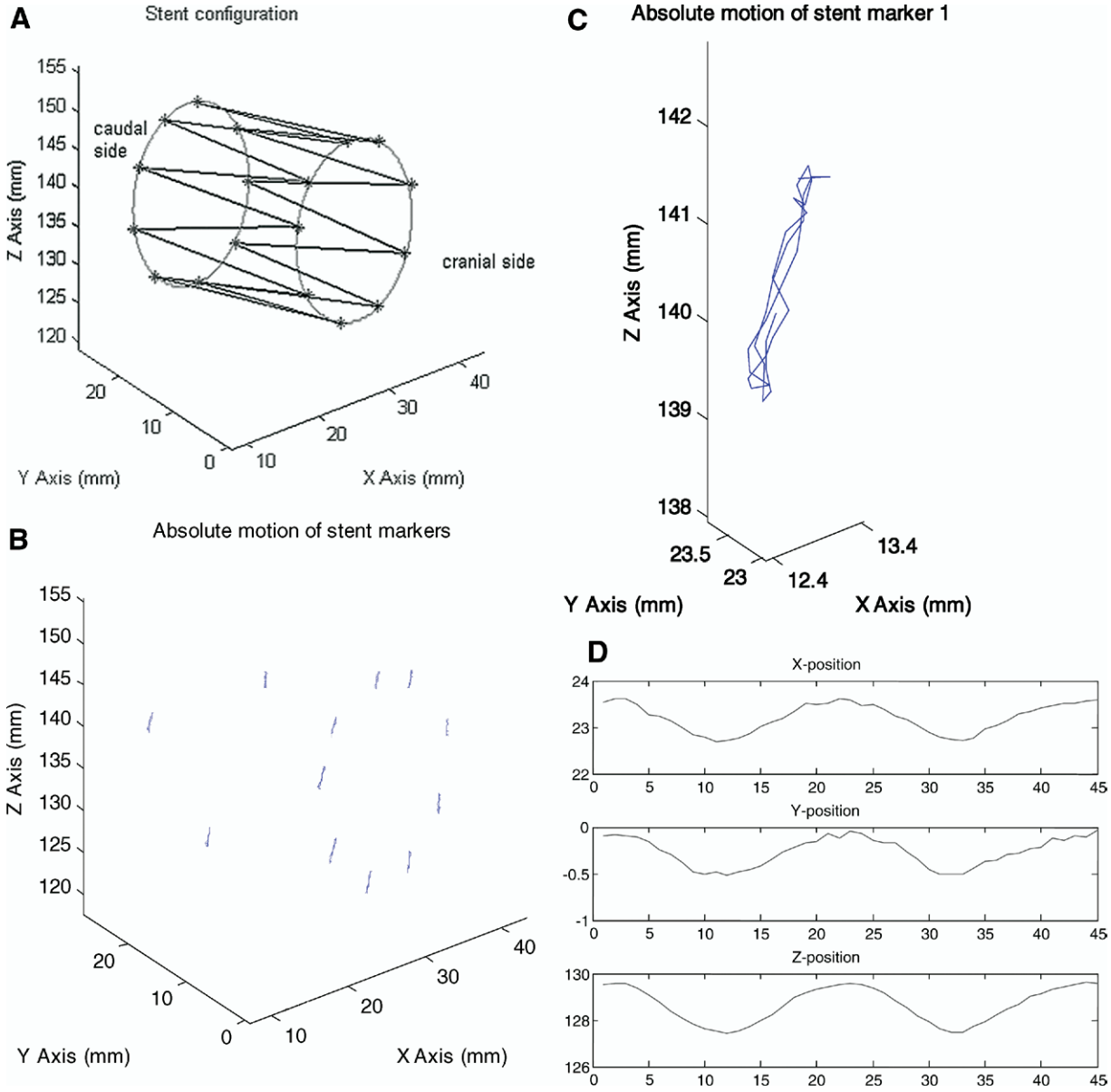

Fig 7. Three-dimensional motion of the stent-graft markers. (**a**) Drawing of the stent configuration. (**b**) Overview of the motion of 12 stent-graft markers: 9 at the cranial side and 3 at the caudal side. (**c**) Three-dimensional motion of a single stent-graft marker plotted in the x, y, and z directions. (**d**) Motion analysis of a stent-graft marker; breakdown in motion is shown in the x, y, and z directions. The x-axis depicts the images (1-45), and the y-axis depicts the position relative to the laboratory coordinate system (millimeters).

invasive technique enables quantifying clinical assessment of three-dimensional motion of a stent graft in vivo at a high frame rate. This method is extremely important because the effects of pulsatile flow and stent graft design on motion of the various stent graft parts can be measured in real time, in detail. Until now, this was impossible. FRSA may provide information that is crucial for further improvements in stent-graft design.

The use of CT and MRI for assessment of stent-graft motion has been reported, but these techniques are limited to the measurement of motion in a single plane.[3-5] Furthermore, the accuracy and reproducibility of these measurements have not been validated. This limitation to single-plane analysis prevents analysis of the complex motion patterns that occur differently in the various stent grafts during the cardiac cycle, including axial, transverse, and rotational components.[3-5,16] This technical limitation of CT and MRI is caused by the fact that there currently is no technique available to follow a specific point (marker) of the graft in time through the four-dimensional image data

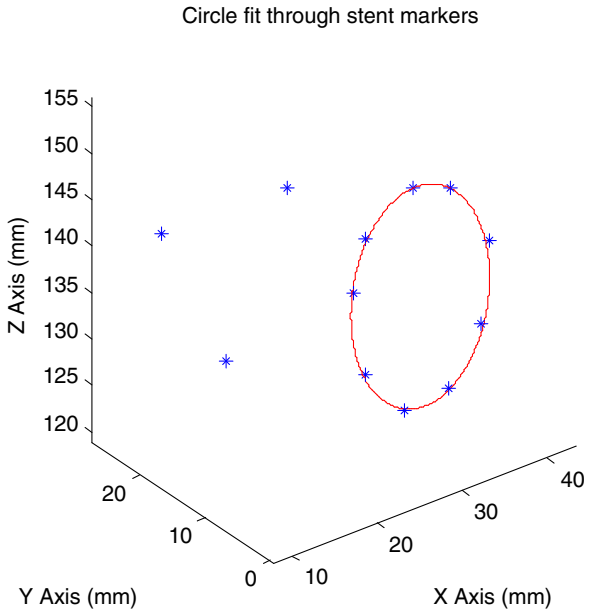

Fig 8. Circle fit through the nine cranial stent markers.

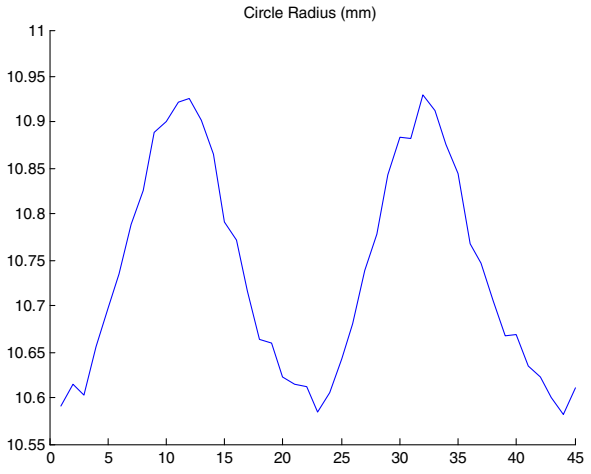

Fig 9. Change in radius of the circle in millimeters (y-axis), as fitted through the 45 images (x-axis).

set. Moreover, application of MRI is limited because certain stent grafts cause significant artifacts in MRI images.

Single-focus fluoroscopic measurement of marker motion has been used to assess joint kinematics in orthopedic applications by using single-plane images. This method is accurate parallel to the image plane (reported measurement error, 0.1-0.17 mm), but out-of-plane measurement error is relatively large (0.7-1.9 mm).[14,17] Furthermore, this technique requires a fixed configuration of at least three markers to enable reconstruction of the position of the implant. This fixed configuration cannot be achieved in the dynamic structure of current stent grafts, thus making single-focus fluoroscopy inappropriate for application in EVAR evaluation.

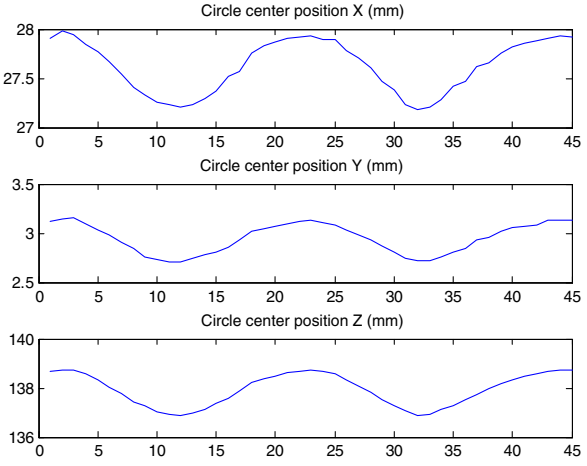

Fig 10. Change of position of the circle center. The x-axis depicts the images (1-45), and the y-axis depicts the position relative to the laboratory coordinate system (in mm).

In this study, we used two sets of markers. One was the tantalum marker, a highly radiopaque, spherical marker, which results in the best possible measurement in orthopedic RSA. This kind of marker could be added to the stent graft by the manufacturer. The other marker we used was a drop of welding tin. These already occur in certain stent grafts that are currently in wide clinical use. Markers that are used for positioning of the graft during EVAR can also be used for this procedure. Alternatively, automated pattern recognition of the stent graft could be used to facilitate measurements without the need for markers. These aspects of FRSA are subject to further evaluation at our institution. In contrast to RSA, used to detect graft migration during follow-up,[12,13] no additional markers are needed in the wall of the aorta to perform these dynamic measurements. The spine markers used in our study were solely used for this experiment to determine measurement precision and as an internal control. They were not used to determine the actual stent motion. This determination is done by independently reconstructing the position of each stent marker in space in the sequential images acquired by the calibrated setup and calculating the marker displacement between these consecutive images.

Limitations. A model was used to study pulsatile change in an aorta with a stent graft. Patient studies have to be undertaken to assess the quality of the images and the visibility of the markers of a stent graft in vivo, surrounded by soft tissue. However, when considering the image quality of clinical cardiovascular studies acquired by the Siemens setup and the validation of FRSA as demonstrated in this study, we are certain that analysis of patient images is feasible; therefore, analysis of stent-graft motion in vivo can be performed.

Different commercially available stent grafts have different markers. In this study, only one graft design was tested. On the basis of our experience with RSA, including pilot testing of imaging and detectability of markers on

different commercially available stent grafts, we believe that motion analysis of different commercially available grafts is feasible. This issue is subject to further study at our institution.

Practical applications. Further detailed knowledge of stent-graft motion during the cardiac cycle is required to better understand the in vivo behavior of stent grafts after EVAR. New stent grafts can be evaluated, as can existing grafts. With this knowledge, virtual mechanical modeling becomes possible, and assessment of the failure modus of the stent graft, such as failure due to metal fatigue, is facilitated. On the basis of clinically acquired, detailed knowledge of stent-graft motion, forces acting on the stent graft during the cardiac cycle can be calculated more accurately. With this knowledge, it is possible to evaluate preclinical bench-testing of stent grafts and verify its adequacy. Bench-testing itself will be improved according to in vivo measured clinical data. Knowledge of in-vivo stent-graft motion should be an important adjunct in phase I clinical evaluation of stent grafts. Withdrawal of a graft from the market because of mechanical defects that arise after widespread introduction could be prevented with better bench-testing and early detection of unexpected graft motion.

The radiation dose of FRSA was determined in a separate, unpublished experiment by our clinical physicists. The radiation dose is approximately 0.1 mSv for a 3-second study; this corresponds to 4 cardiac cycles at a heart rate of 80 per minute. This compares very favorably to the 17-mSv dose of triple-phase CT scan used for EVAR follow-up.

CONCLUSION

In this study, FRSA has proven to be a method with very high accuracy and temporal resolution to measure three-dimensional stent-graft motion in a pulsatile environment. This technique has the potential to contribute significantly to the knowledge of stent-graft behavior after EVAR and improvements in stent-graft design. The technique is ready for clinical testing.

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AUTHOR CONTRIBUTIONS

Conception and design: OHJK, BLK, EHG, JWH, ERV, JHvB
Analysis and interpretation: OHJK, BLK, EHG, JWH, JFH, ERV, JHvB
Data collection: OHJK, BLK, EHG, JWH, JHvB
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Critical revision of the article: OHJK, BLK, EHG, JWH, JFH, ERV, JHvB
Final approval of the article: OHJK, BLK, EHG, JWH, JFH, ERV, JHvB
Statistical analysis: OHJK, BLK, EHG, JHvB
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Overall responsibility: OHJK

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